PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Smart Medical Systems Ltd. 10 Hayetsira Street 43663 Ra'anana Israel	PCT NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION			
	(PCT Rule 44.1)			
	Date of mailing (day/month/year) 1 SEP 2009			
Applicant's or agent's file reference	FOR FURTHER ACTION See paragraphs 1 and 4 below			
67777	TOM TOM TOWN THE TOWN			
International application No. PCT/IL 09/00322	International filing date (day/month/year) 23 March 2009 (23.03.2009)			
Applicant SMART MEDICAL SYSTEMS LTD.				
1. The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith. Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):				
When? The time limit for filing such amendme international search report.	rits is normally two months from the date of transmittal of the			
Where? Directly to the International Bureau of WI 1211 Geneva 20, Switzerland, Facsimile?	PO, 34 chemin des Colombettes No.: 441 22 338 8270			
For more detailed instructions, see the notes on the	e accompanying sheet.			
2. The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.				
3. With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:				
the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.				
no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.				
4. Reminders Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication. The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an				
international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.				
Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.				
months.	months (or later) will apply even if no demand is filed within 19			
See the Annex to Form PCT/IB/301 and, for details about the Guide, Volume II, National Chapters and the WIPO Internet	e applicable time limits, Office by Office, see the PCT Applicant's site.			
Name and mailing address of the ISA/US	Authorized officer:			
Mail Stop PCT, Attn: ISA/US	Les W. Young			
Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	PCT Helpdesk: 574-272-4300 PCT OSP: 571-272-7774			
Pacamine (vo. 47 response)				

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 67777	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.			
International application No.	International filing date (day/	(month/year) (Earliest) Priority Date (day/month/year)			
PCT/IL 09/00322	23 March 2009 (23.03.2009)	31 March 2008 (31.03.2008)			
Applicant SMART MEDICAL SYSTEMS LTD.					
according to Article 18. A copy is bein This international search report consists	g transmitted to the Internationa /	•			
1. Basis of the report	***				
a. With regard to the language, th	e international search was carrie	ed out on the basis of:			
the international app	olication in the language in whic	ch it was filed.			
a translation of the i	international application into	which is the language of onal search (Rules 12.3(a) and 23.1(b)).			
a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)). b. This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).					
		ace disclosed in the international application, see Box No. I.			
2. Certain claims were four	nd unsearchable (see Box No. I	II).			
3. Unity of invention is lack	dng (see Box No. III).				
4. With regard to the title,					
the text is approved as sub	omitted by the applicant.				
the text has been established by this Authority to read as follows:					
5. With regard to the abstract,	$(\mathcal{A}_{i})_{i} = (\mathcal{A}_{i})_{i} = (A$				
the text is approved as sub	omitted by the applicant.				
the text has been establish may, within one month from	ted, according to Rule 38.2(b), born the date of mailing of this into	by this Authority as it appears in Box No. IV. The applicant creational search report, submit comments to this Authority.			
6. With regard to the drawings,					
a. the figure of the drawings to b	·	Figure No. 1			
as suggested by the					
	Authority, because the applicant				
as selected by this A	Authority, because this figure be	tter characterizes the invention.			
b none of the figures is to b	e published with the abstract.				

Form PCT/ISA/210 (first sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No. PCT/IL 09/00322

Box No.	If Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)				
This inte	mational search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:				
t \square	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:				
2.	Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:				
3. 🔯	Claims Nos.: 4-9, 17, 22, 23, 30-32 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).				
Box No.	Observations where unity of invention is lacking (Continuation of item 3 of first sheet)				
	rnational Searching Authority found multiple inventions in this international application, as follows:				
Pleas	se see supplemental Sheet				
	·				
1.	As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.				
2.	As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.				
3.	As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:				
4. 🔀	No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-3, 10-13				
Remark	on Protest The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.				
	The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.				
	No protest accompanied the payment of additional search fees.				

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No. PCT/IL 09/00322

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 1/012 (2009.01) LISBO 800/121						
According to	USPC - 600/121 secording to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELD	OS SEARCHED					
	cumentation searched (classification system followed by 3 1/012 (2009.01) 121	classification symbols)				
600/101, 116	Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched 300/101, 116 A61B 1/00 (2009.01)					
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) PubWEST(USPT,PGPB,EPAB,JPAB); Google Scholer; Search Terms Used: endoscope, catheter, elongate member, tubular member, mount\$, install\$, manufactur\$, assemb\$, balloon, resilient member, expan\$, sheath, cover						
C. DOCUMENTS CONSIDERED TO BE RELEVANT						
Category*	Citation of document, with indication, where ap	ppropriate, of the relevant passages	Relevant to claim No.			
x	US 2005/0125005 A1 (FUJIKURA) 09 June 2005 (09.0 para[0041]-[0048], para[0072] and FIGS, 4A-4D, 9 and	v1 (FUJIKURA) 09 June 2005 (09.06,2005) Entire document, especially sers[0072] and FIGS, 4A-4D, 9 and 14-15.				
Y			1-3			
Y	Y US 4,646,988 A (CAMPBELL) 03 March 1987 (03.03.1987) Entire document, especially col 2, in 59 - col 3, in 50 and FIGS. 1, 3.		1-3			
	r documents are listed in the continuation of Box C.					
"A" documen	categories of cited documents: nt defining the general state of the art which is not considered particular relevance	"T" later document published after the inte date and not in conflict with the appl the principle or theory underlying the	cation but cited to understand			
"E" earlier a filing da	pplication or patent but published on or after the international ste	considered novel or cannot be consi	dered to involve an inventive			
cited to	nt which may throw doubts on priority claim(s) or which is establish the publication date of another citation or other reason (as specified)	step when the document is taken alor "Y" document of particular relevance; the considered to involve an inventive	claimed invention cannot be			
"O" docume means	nt referring to an oral disclosure, use, exhibition or other	combined with one or more other such being obvious to a person skilled in t	documents, such combination			
the prior	nt published prior to the international filing date but later than rity date claimed					
	octual completion of the international search	Date of mailing of the international sea	ren report			
Name and m	ailing address of the ISA/US	Authorized officer:				
Mail Stop PC P.O. Box 145	T, Attn: ISA/US, Commissioner for Patents 0, Alexandria, Virgini≘ 22313-1450 o. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774	1			

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IL 09/00322

Continuation of Bon No. III; Observations where unity of Invention is lacking (Continuation of item 3 of first sheet)

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-3, 10-13 directed to an expander device

Group II: claims 14-16, 18 directed to a coller cutting tool

Group III; claims 19-21, 24-26 directed to a double balloon assembly

Group IV: claims 27-29, 33-39 directed to a wrap around accessory

The groups of inventions above do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The species technical feature of the Group I claims is a chassis element that engages a resilient tubular article, which is not present in the claims of Groups II-IV. The special technical feature of the Group II claims is a cutting edge for cutting a collar, which is not present in the claims of Groups I or III-JV. The special technical feature of the Group III claims is a forward and rear balloon, which is not present in the claims of Groups I-II or IV. The special technical feature of the Group IV claims is an assectory which wraps around the endoscope with a slit, which is not present in the claims of Groups I-III. Therefore, the listed Inventions lack unity of Invention under PCT Rule 13 because they do not share a same or corresponding special technical feature. Claims 4-9, 17, 22, 23, 30-32 are improper multiple dependent claims not in compliance with PCT Rule 6.4 (a).

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY				
To: Smart Medical Systems Ltd. 10 Hayetsira Street 43663 Ra'anana Israel	PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)			
	Date of mailing (day/month/year) 1 SEP 2009			
Applicant's or agent's file reference 67777	FOR FURTHER ACTION See paragraph 2 below			
International application No. International filing	date (day/month/year) Priority date (day/month/year)			
PCT/IL 09/00322 23 March 2009	(23.03.2009) 31 March 2008 (31.03.2008)			
International Parent Classification (IPC) or both national classification and IPC IPC(8) - A61B 1/012 (2009.01) USPC - 600/121				
Applicant SMART MEDICAL SYSTEMS LTD.				
1. This opinion contains indications relating to the following items: Box No. I Basis of the opinion				
 2. FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. 3. For further details, see notes to Form PCT/ISA/220. 				
Name and mailing address of the ISA/US Mail Stop PCT, Attr. ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young POT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774			

Form PCT/ISA/237 (cover sheet) (April 2007)

International application No.

PCT/IL 09/00322

Box	No. I	Basis of this opinion
1.	With r	egard to the language, this opinion has been established on the basis of:
	\times	the international application in the language in which it was filed.
		a translation of the international application into which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2.		This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3,		egard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been shed on the basis of:
	я. тур	pe of material
		a sequence listing
	C.	table(s) related to the sequence listing
	b. for	mat of material
		on paper in electronic form
	L	in electronic torm
	ç. tin	ne of filing/furníshing
		contained in the international application as filed
		filed together with the international application in electronic form
	Ī	furnished subsequently to this Authority for the purposes of search
4.		In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5	A ddit	ional comments:
۷,	ALGOR.	one constants.
		·
:		

International application No.

PCT/IL 09/00322

Box No. 1	II Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
	ions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially the hot been examined in respect of
	the entire international application
∇	4-9, 17, 22, 23, 30-32 claims Nos.
	cialins Nos.
becaus	¢:
	the said international application, or the said claims Nos relate to the following subject matter which does not require an international search (specify):
Claims 4-9	the description, claims or drawings <i>(indicate particular elements below)</i> or said claims Nos. 4-9, 17, 22, 23, 30-32 are so unclear that no meaningful opinion could be formed <i>(spectfy)</i> : 3, 17, 22, 23, 30-32 are improper multiple dependent claims not in compliance with PCT Rule 6.4 (a).
	the claims, or said claims Nos are so inadequately supported by the description that no meaningful opinion could be formed (specify):
\boxtimes	no international search report has been established for said claims Nos. 4-9, 17, 22, 23, 30-32
	a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
L	furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable
	to it. furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable
	to it. pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).
	a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.
	the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
	See Supplemental Box for further details.

Form PCT/ISA/237 (Box No. III) (April 2007)

International application No.

PCT/IL 09/00322

Box No. IV Lack of unity of invention
1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
paid additional fees
paid additional fees under protest and, where applicable, the protest fee
paid additional fees under protest but the applicable protest fee was not paid
not paid additional fees
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
complied with
not complied with for the following reasons:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
Group I: claims 1-3, 10-13 directed to an expander device Group II: claims 14-16, 18 directed to a collar cutting tool
Group III; claims 19-21, 24-26 directed to a double balloon assembly Group IV: daims 27-29, 33-39 directed to a wrap around accessory
The groups of inventions above do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
The special technical feature of the Group i claims is a chasels element that engages a resilient tubuler article, which is not present in the claims of Groups II-IV.
The special technical feature of the Group II claims is a cutting edge for cutting a collar, which is not present in the claims of Groups I or
The special technical feature of the Group III claims is a forward and rear balloon, which is not present in the claims of Groups I-II or IV. The special technical feature of the Group IV claims is an asseccory which wraps around the endoscope with a slit, which is not present in the claims of Groups I-III.
Therefore, the listed inventions lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.
4. Consequently, this opinion has been established in respect of the following parts of the international application:
all parts
the parts relating to claims Nos. 1-3, 10-13

International application No.

PCT/IL 09/00322

, Statement			
		4 0 44 40 49//44 49\	
Novelty (N)	Claims	1-3, 11-12, 13/(11-12) 10, 13/(10)	YES
	Claims	10, 13/(10)	NO
(35)	Claims	None	YES
Inventive step (IS)	Claims	1-3, 10-12, 13/(10-12)	NO
Industrial applicability (IA)	Claims	1-3, 10-12, 13/(10-12).	YES
	Claims	None	NO
per claim 10. Fujikura describes a mei ploying an expander (10; FIGS. 4) con chassis element (16) which is selectably illient portion of said resilient outer tubilitiver (14) which is movable with respect engagement element (18) configured to delongate article (14), carry out the following functions: pending said at least one resilient portioned by insertion of said engagement lowed by engagement of said elongate lowed by disengagement of said engagement at a lateral management and engagement and	thod for moun nprising: y engageable alar article (12 ct to said char to accommod on (12A) of sa element (18) article (14) w gement eleme method of mo	., para[0042]); ṣṣiṣ (FIGS. 4);	a[0041]) compri
aims 11-12 and 13/(11,12) lack an inve	ntive step und	der PCT Article 33(3) as being obvious over Fujikura.	
it faile to describe and also comprising t	following said cle with said e nent of said er	nting a resilient outer tubular article over an elongate article acc Insertion of said engagement element into said at least one resingagement element, the step of disengagement of said engage agagement element from the user's hand (FIGS. 4B-4C). It is a common tool such as forceps, or to make a custom tool ement and remainder of expander device as this would decreas	illent portion, an iment element fr as part of the
owever, Fujikura describes disengagem would have been obvious to one skilled pander so as to create a removable et	ngagement ek	e with his hends.	e contamination
powever, Fujikura describes disengagem would have been obvious to one skilled control of the variety of the var	ngagement eliding the device the thick of mount following sald element from ider. It of said engagement eliting the device es a method conent of said element of said element of said element of said element device es a method conent of said element device es a method conent of said element device es a method conent of said element device element of said element device element elem	with his hands. Inting a resillent outer tubular article over an elongate article accidengagement of said elongate article with said engagement elesaid at least one resilient portion, the step of engagement of said at least one resilient portion, the step of engagement of said at least one resilient portion, the step of engagement of said gement element from the user's hand (FIGS. 4D). It lize a common tool such as forceps, or to make a custom tool ement and remainder of expander device as this would decreas	cording to claim ment, and prior id engagement as part of the e contamination

International application No.

PCT/IL 09/00322

Suc	anle	mei	ntal	Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
-----Box V.2. Citations and explanations---

Claims 1-3 lack an inventive step under PCT Article 33(3) as being obvious over Fujikura in view of US 4,646,988 A to (Campbell).

As per claim 1, Fujikura describes an expander for mounting a resilient outer tubular article over an elongate article (para[0002]) comprising:

a chassis element (116, FIG. 9) having associated therewith at least one outwardly

movable element (118) which is selectably engageable with at least a portion of said resillent outer tubular article (112; para[0072], FIGS.

a driver (14, FIGS, 4) which is movable with respect to said chassis element and is

operative to selectably engage said at least one outwardly movable element, when said-

outwardly movable element is in engagement with said at least a portion of said resilient

outer tubular article, for producing corresponding outward motion and outward expansion

thereof (para[0047], FIGS. 4, 14-15).

But fails to describe an engagement element, associated with said driver, for insertion into said at least a portion of said resilient outer tubular article upon expansion thereof by operation of said driver, said engagement element being configured to accommodate at least a portion of sald clongate article.

However, Campbell describes an outer tubular article to be mounted around a clongate article (Abstract) in which an engagement element (35, FIGS. 1, 3; col 3, In 25-36) associated with the driver (10) for insertion into said at least a portion of said outer tubular article upon expansion thereof by operation of said driver (FIGS, 1.3), said engagement element being configured to accommodate at least a portion of said eiongate article (11; col 3, în 37-50).

It would have been obvious to one skilled in the art to implement a separate drive member with an engagement element for engaging the elongate tubular member as described by Campbell on the device of Fujikura so as to allow the elongate member to be pulled into the resilient article, as this gripping of the elongate member frees up a user hand and thus allows for operation by a single user.

As per claim 2, Fullkurs and Campbell describe an expander according to claim 1, Campbell further describes and also comprising resilient outer tubular article disengagement functionality operative for disengagement of said at least a portion of said resilient outer tubular article from said engagement element (col 2, In 59 - col 3, In 24).

As per claim 3, Fujikura and Campbell describe en expander according to claim 1 or claim 2, and Campbell further describes and wherein said disengagement functionality is associated with said chassis element (col 2, in 59 - col 3, in 24; FIGS. 1, 3).

Claims 1-3, 10-12 and 13/(10-12) have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.